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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,739	11/08/2001	James C. Copeland	OXR 2 0025	4971

7590 07/10/2006

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,739	COPELAND ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-13,16-26,20-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-13,16-26 and 20-36* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1–4, 7-13, 16-26, 28-36 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 05, 2006 has been entered.

Allowable Subject Matter

1. . Claim 2 is objected to as being dependent upon a rejected base claim, and is rejected under 35 USC 112, but would be allowable if rewritten in independent form including all of the limitations of the base claim, and obviating the rejection under 35 USC 112.

Rejections Withdrawn

1. . The rejections of claims 6 and 8 (paragraph d) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been obviated in light of the cancellation of claim 6 and the amendment of claim 8.

Rejections Maintained

2. Claims 1, 3-4, 7-13, 16-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record and responses set forth below

3. Claims 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) for reasons of record and responses set forth below.

4. Claims 1, 3-4, 7-13, 16-26, 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992). in view of Copeland et al (US Pat. 5,830,746) for reasons of record and responses set forth below.

5. Claims 1, 3-4, 7-13, 16-26 and 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Fung (US Pat. 5,405,773) for reasons of record and responses set forth below.

Rejections Maintained/ Response to Arguments

1. Applicant's arguments filed April 5, 2006 have been fully considered but they are not persuasive.

2. General Remarks set forth by Applicant will be briefly addressed.

3. Applicant asserts that Adler and PG-Pub 2002/0045245 do not define the membrane fragments to comprise glucose oxidase or alcohol oxidase enzymes.

4. It is the position of the examiner that upon reconsideration of paragraph [0029] of PG-Pub 2002/0045245, the examiner found the PG-Pub to cite US Pat. 4,476,224, and referred to the bacterial membrane fractions described there in and went on to state "Other known biocatalytic oxygen reducing agents such as glucose oxidase, alcohol oxidase, etc. can also be utilized". Clarification of this quoted statement is found in issued Patents to Adler and Copland, specifically US Pat. 5,955344, claims 27-29 and US Pat. 5,830,746, claims 17-19, which define the **bacterial membrane fraction** to comprise glucose oxidase and catalase.

With respect to cited evidence for showing biological effects of azide or cyanide on either anaerobic bacterial or other microbes, the examiner's prior response included evidence directed to these effects relative to the claimed invention and the applied prior art.

5. Applicant's statements directed to eukaryotes is not what is now claimed, and was not the examiner's focus in the last Office Action Response to Arguments (See pages 3-4 of the Office Action mailed November 1, 2005).

Various combinations of enzymes with azide or cyanide were cited. The effect of azide or cyanide on anaerobic and other microbial enzymes were discussed for the purpose of showing

that cyanide or azide would not kill the enzyme activity resulting in lack of anaerobic growth. The compositions included:

- anaerobe ATPase and azide (Milgrom et al (1988) (ATPase being indicative of energy utilization and growth),
- anaerobic bacterial growth in the presence of azide or cyanide (Merad et al and Hope et al).
- E. coli membranes and azide (see Sjogren et al, Tabakhovskii),
- catalase together with azide (Tillonen et al)
- glucose oxidase and azide (microbial fungi previously cited; but Pseudomonas, 1973, Fig. 3,p145, cited herein)

The examiner sought to show that the presence of :

- azide or cyanide in anaerobic growth media allows growth of bacterial anaerobes (Merad and Hope et al) over facultative anaerobes,
- that most of enzymes present in bacterial membrane fractions obtained from, for example Escherichia coli, could still function in the presence of azide (see Sjogren et al; Tabakhovskii et al), and
- catalase present in aerobic and facultative bacteria would be inhibited by azide (Tillonen et al (1998), abstract, middle line "catalase inhibitors sodium azide")..

In re Kerkhoven (205 USPQ 1069 CCPA 1980) summarizes " It is prima facie obvious to combine two compositions (medium plus oxygen scavenging bacterial membrane fragments & medium plus azide) each of which is taught by prior art to be useful for the same purpose (in the instance selective medium for growth of anaerobic bacteria) in order to form a third composition

that is to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in prior art.".

6. The rejection of claims 1, 3-4, 7-13, 16-26 under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) is traversed on the grounds that 0.1% azide would inhibit the membrane fragments of Adler.

7. It is the position of the examiner that evidence n previously cited showed azide to only moderately inhibit E.coli growth. Sjogren et al showed azide inhibited E.coli about 15% and Tillonen et al provided evidence showing azide to inhibit catalase present in aerobic and facultative aerobic bacteria. The membrane fractions obtained from E.coli (instant claim 13) comprise additional oxygen scavenging components, and would still serve to scavenge oxygen. Actually, the 0.1% azide concentration of Merad et al, is equal to 0.01 mg/ml which is Applicant's claimed lower limit for azide supplementation to the medium (see instant claim 3).

8. Applicant states "Neither Merad nor Adler teach that enzymes on membrane fragments are resistant to 0.1% azide.

6. It is the position of the examiner that the instant Specification [0050] defines the membrane fragments to be "biocatalytic oxygen reducing agents" which are defined to include **bacterial membrane fractions** that comprise glucose oxidase and catalase (Patents to Adler and Copland, specifically US Pat. 5,955344 (issue date 1999) claims 27-29 and US Pat. 5,830,746, claims 17-19, (issue date 1998)). Glucose oxidase, albeit, fungal or bacterial

(Pseudomonas reference cited above) is only partially inhibited by azide (see discussion above) and would therefore still function in the presence of azide in growth media.

9. The rejections of claims 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224) ; Claims 1, 3-4, 7-13, 16-26, 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992). in view of Copeland et al (US Pat. 5,830,746) ; and Claims 1, 3-4, 7-13, 16-26 and 28-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Fung (US Pat. 5,405,773) are traversed by asserting "There is still no motivation to combine"

10. It is the position of the examiner that :

a. **Aldle**r teaches the advantage of overcoming the disadvantage of employing cumbersome physical techniques,

"jar for anaerobiosis, see page 4, English translation Merad et al" which is used by Merad et al.

Adler et al specifically state: "When these organisms (known as anaerobes) are brought into the laboratory, it is often necessary to employ cumbersome physical and chemical techniques in order to get them to grow. Some of these bacteria produce diseases of man and related species. Other produce important industrial end products such as methane, hydrogen and various alcohols. The manipulation of these organisms is, to some degree, limited by the ease with which they can be grown (see col. 1 of Adler). "

b. **Copeland** et al teach **disadvantages** of utilizing traditional anaerobic growth conditions, which employ:

" many culture dishes, a sealed table-top chamber can be used (Anaerobe Systems, San Jose, Calif.). This chamber is evacuated and flushed with inert gases, such as nitrogen and/or carbon dioxide. Sometimes chemicals and a catalyst are used to consume the oxygen inside the chamber and fresh, inert gas is supplied as needed. The microbiologist works with the culture dishes inside of this chamber through ports fitted with gloves. A means is provided for introducing materials into and taking items out of the chamber without breaching the anaerobic environment inside.

Work with microaerophiles and anaerobes under these conditions is labor intensive, difficult, expensive, and time consuming. The microbiologist is often frustrated by having to wait for the slowest growing microbe in order to retrieve all culture dishes from a bag or jar since once the bag or jar is opened, the microbes are exposed to oxygen. A failure in the system can be catastrophic for all of the microbial isolates inside. "

Copeland et al teach the advantage of employing:

The present inventors have designed a novel culture apparatus or dish in order to eliminate many of the difficulties observed in the prior art. It has been found that the use of the new culture dish (i.e., "OxyDish ") together with an oxygen reducing agent (preferably a biocatalytic oxygen reducing agent) and, in some instances, a substrate, produces a controlled, self-contained environment "

c. Fung et al **teaches the advantage** of "an improved assay for the determination of motile facultative anaerobic pathogens, and especially L. monocytogenes, in samples such as meat. More particularly, it is concerned with such an assay which makes use of a substance such as an **oxygen-reactive enzyme (e.g., oxyrase enzyme)** for enhancing the growth rate of a target pathogen in a selected growth medium**, in order to materially lessen the amount of time required for completing the assay**. Assays for determining the presence of L. monocytogenes in meat samples can be completed in times many hours shorter than previous standard assays. "

1. Adler et al and Copeland provide motivation for the addition of the oxygen scavenging membrane fragments into the growth media of Merad et al to relieve the laboratory worker from working with cumbersome physical equipment such as anaerobic jars. And Fung et al provides motivation to modify the media of Merad et al to "materially lessen the amount of time required for completing the assay (Fung et al)." Therefore the applied prior art clearly teaches and provides motivation for combining the oxygen scavenging membrane fragments from any one of Adler, Copeland or Fung into the growth medium of Merad et al because Merad et al employed a jar for anaerobiosis and Adler, Copeland and Fung all teach that through supplementing growth media with the oxygen scavenging membrane fragments, the disadvantages of employing cumbersome physical equipment without interfering with anaerobic conditions and Fung et al teaches that the amount of time required for completing the assay is materially lessened.

New Grounds of Rejection

Claim Objections

11. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends from claim 1 and modifies a sample which is not the claimed invention of claim 1, the term "sample" appears in claim 1, but is apart of the recited intended use of the claimed composition; modification of a recited intended use of a composition does not further limit the claimed invention as not structural components of the composition have been modified.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 and all claims dependent therefrom (2-4, 7, 9) and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Claim 1 recites the phrase "self-generating anaerobic medium"; original descriptive support for this phrase could not be found in the instant Specification and therefore is new matter.

15. Claim 8 is objected to because of the following informalities: Claim 8 in paragraph e. recites the phrase "inoculated liquid medium composition containing the azide"; the liquid medium recited is not just a liquid with azide, but a liquid with azide and oxygen scavenging fragments. No compositions with just liquid and azide are recited in the claim. No other liquids are recited in the claim. Clarification of this phrase is requested . Appropriate correction is required.

16. Claims 1, 7, 20-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Howell et al (September 18, 2000) in light of product description (MSDS, Oxyrase, Inc.).

Howell et al disclose the instantly claimed invention directed to a medium composition that comprises:

hydrogen donating substance in saline, (saline supplemented with (see page 1235, col. 2, p. 3, line 6) deoxyglucose (pg 1235, col. 2, p. 3, line 7 (1 mM)) a type of nutrient medium,

sodium azide (see page 1235, col. 2, paragraph 3, line 6 (5 mM)), and

Oxyrase (oxygen scavenging membrane fragments (see product narrative, 0.3 U/ml) "Enzymes of Escherichia coli", Material Safety Data Sheet, section A.)

Howell anticipates the instantly claimed invention as now claimed in light of fact that the recited intended use of the claimed composition does not define over the applied prior art that discloses a composition with the claimed combination of components.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Underground tank technology Update March/April 1998, Vol. 12(2) is cited to show the addition of sodium azide (see page 2, col..1, bottom half) and Oxyrase for creating an anaerobic growth environment for bacteria (see page 2, col. 2, 4th paragraph).

9. US 20030138874A1 US006153400A US 20030124643A1 US007018828B1 US 20030138874A1 are cited to show culture mediums for the growth of microorganisms and contain membrane fragments having an oxygen transfer system.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
June 20, 2006

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